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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/693,121	10/20/2000	Jeffrey Schlom	45394	7805

7590

01/21/2004

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 01/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/693,121

Applicant(s)

SCHLOM ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-29 is/are pending in the application.
- 4a) Of the above claim(s) 21 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-20, 22 and 24-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed 9/29/2003 is acknowledged and entered into the record. Accordingly, claims 17-19 are amended.
2. Claims 17-29 are pending, claims 21 and 23 are withdrawn from further prosecution as being drawn to a non-elected invention.
3. Claims 17-20, 22, 24-29 are examined on the merits.

Terminal Disclaimer

4. The terminal disclaimer filed on 9/29/2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6,165,460 has been reviewed and is accepted. The terminal disclaimer has been recorded.

New Arguments

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting

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directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 17-19, 24-26 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Spitler *et al* (US Patent 5,925,362). Claims are drawn to a method of generating an immune response to PSA in a host comprising the administration of PSA or a cytotoxic T-cell eliciting epitope thereof, and an effective amount of a cytokine or co-stimulatory molecule (claim 17). The claims are further drawn to at least a periodic interval thereafter the administration of a sufficient amount of additional PSA or cytotoxic T-cell eliciting epitope thereof to boost the immune response (claim 18); the administration of the boosting amount of PSA by a pox virus vector comprising a DNA segment encoding PSA or a cytotoxic T-cell eliciting epitope thereof linked to a promoter (claim 19); the PSA or cytotoxic T-cell eliciting epitope is formulated with an adjuvant or is in a liposomal formulation (claim 24), wherein the adjuvant is selected from the group consisting of RIBI Detox, QS21, and incomplete Freund's adjuvant (claim 25); wherein the cytokine is IL-2, IL-6 or IL-12 (claim 26), and wherein the method comprises the further addition of additional cytokine or co-stimulatory molecule (claim 28).

Spitler *et al* teach and claims a method of inducing an anti-tumor immune response comprising the administration of a formulation comprising PSA and cytokines (column 2, lines 45-55). It is further disclosed by Spitler *et al* that the formulation of the PSA and cytokine can be administered more than once as "booster inoculations"

(column 9, line 1-6). Further still, Spitler *et al* disclose that PSA can be incorporated into pox viral vectors and that such pox viral vectors can be vaccinia vectors (column 7 lines 3-15 and column 9, lines 12-15). Spitler *et al* also disclose that the formulation can be administered in conjunction with cytokines such as IL-2, and that additional cytokines can be administered with additional PSA (column 7, lines 52-67).

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 17-20, 22, 24-26 rejected under 35 U.S.C. 103(a) as being unpatentable over Spitler *et al* in view of Fields *et al* (Fields Virology 3rd Edition Vol. 2. Lippincott, Williams, and Wilkins, pages 2637-2671) and Hodge *et al* (Cancer Res. 1994;

54(21):5552-5, cited previously). See above for limitations to claims 17-19, 24-26 and

28. The claims are further drawn to the pox virus being selected from the group consisting of suipox, avipox, capripox, and orthopox (claim 20), wherein the avipox is fowlpox, canary pox, pigeon pox (claim 22); wherein the co-stimulatory molecule is selected from the group consisting of B7.1 and B7.2 (claim 27), and the pox virus further contains a DNA encoding a cytokine or co-stimulatory molecule (claim 29).

See above for Spitler *et al* disclosure. What Spitler *et al* do not disclose or teach is the specific types of pox viruses such as suipox, avipox (fowl pox, canary pox, pigeon pox), and capripox, claimed, nor do they teach the specific B7.1 and B7.2 co-stimulatory molecules. These deficiencies are made up by both Fields *et al* and Hodge *et al*.

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Fields *et al* provides the general disclosure of the different pox viruses and further provides the motivation to use such viral vectors for gene transfer (see page 2639 and 2659). Hodge *et al* provides disclosure on the specific co-stimulatory molecules B7.1 and B7.2 and their specific anti-tumor immune response elicitation in pox viral vectors.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to induce an immune response to PSA comprising the administration of PSA and a cytokine or co-stimulatory molecule wherein the PSA and the cytokine or co-stimulatory molecule are expressed in a pox virus. One of skill in the art would have been motivated to do so because Spitler *et al* taught that the administration of PSA and a cytokine would be effective for the induction of an anti-tumor immune response, and that such response could be accomplished by the expression of PSA in a pox viral vector such as vaccinia (which is classified under the genera of orthopox) and the co-administration of cytokines or other adjuvants. Moreover, Spitler *et al* provides the motivation to combine with Fields *et al* and Hodge *et al* because Spitler specifically states that other pox viral families are or could be included within the scope of viral vectors, and that the administration of other adjuvants as needed could be used to help enhance the induction of a specific immune response. Both Fields *et al* and Hodge *et al* provide reasonable expectation of success to one of skill in the art in view of Spitler *et al* because both references provide to one of skill in the art reasons for using either different types of pox viruses or provides information that

the use of co-stimulatory molecules are effective on their own when expressed in a pox virus in eliciting a specific immune response.

Therefore, given the method of Spitler *et al*, wherein the method of administering the PSA and a cytokine is effective in inducing an anti-tumor immune response, and the teachings of both Fields *et al* and Hodge *et al*, one of ordinary skill in the art would have found the instant invention obvious.

All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in the amendment filed 9/29/2003.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Man B. Nuliel for:

Christopher Yaen
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December 30, 2003